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CArdiac Death kidney Machine Perfusion trial

Submission date	Recruitment status	[_] Prospectively registered
05/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/09/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/11/2018	Surgery	

Plain English summary of protocol

Background and study aims
There is an international shortage of kidneys for transplantation, and there is great interest in optimising the kidneys available, in order to ensure that kidney transplants last for as long as possible with the best long-term function. When kidneys are recovered from deceased donors they inevitably face a period of storage while they are shipped to the recipient hospital and the logistics of transplantation are put into place. It has been shown that this period of storage can be harmful to kidneys and so this study aims to test which of two commonly used storage techniques is best for kidney transplant outcome. The first technique is 'cold static storage' in which the kidney is placed in cold preservation solution and transported in a box of ice. The second is 'cold pulsatile machine perfusion' in which the kidney is placed on a machine that pumps preservation fluid around the kidney.

Who can participate?
Adult recipients of kidney transplants.

What does the study involve?
Kidneys for transplant will be randomly allocated to either be placed upon the pulsatile perfusion machine or placed in a standard cold-storage ice-box. The kidney transplant recipients will be asked if their information may be followed up.

What are the possible benefits and risks of participating?
Both kidney storage techniques are commonly used in clinical practice outside the study, and we do not anticipate any additional risks from taking part in the study over the standard risks of transplantation but, as many patients will require further transplants, the information gained from this study may help them in future.

Where is the study run from?
The study is being run from Cambridge, with patients from Leeds, Manchester, Edinburgh and Glasgow also taking part.

When is the study starting and how long is it expected to run for?
From April 2011 to May 2017.

Who is funding the study?
NHS Blood and Transplant (UK).

Who is the main contact?
Professor Chris Watson

Contact information

Type(s)
Scientific

Contact name
Prof Chris Watson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A092044 version 1.1

Study information

Scientific Title
A multicentre randomised controlled study of machine perfusion on cardiac death donor kidneys

Acronym
CAD-MP

Study objectives
Cold pulsatile machine perfusion reduces the incidence of delayed graft function in cardiac-death donor kidneys for transplantation, when compared to simple cold storage.

On 26/06/2015 the overall trial end date was changed from 06/08/2012 to 01/12/2016.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, Cambridgeshire 2 Research Ethics Committee, 08/03/2011, ref: 11/H0308/3

Study design
Multicentre randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Kidney transplantion

Interventions
One kidney will be placed upon the LifePort pulsatile perfusion machine. The other will be placed in standard cold-storage ice-box

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Delayed graft function - the need for dialysis within the first week following transplantation

Secondary outcome measures
1. Duration of delayed graft function
2. The area under the curve of the daily serum creatinine level at days 1 to 14
3. Day 14 calculated estimated Glomerular Filtration Rate (eGFR) [abbreviated Modified Diet in Renal Disease (MDRD) technique]
4. The need for dialysis in the first 7 days excluding the first 24 hours post transplant
5. Median times to last dialysis
6. Non-graft function rates, defined as a kidney transplant that fails to provide one month of dialysis free renal replacement, where loss is not attributable directly to rejection or vascular thrombosis
7. Incidence of acute rejection

8. Three and twelve month graft survival
9. Three and twelve month serum creatinine
10. Three and twelve month glomerular filtration rate (MDRD method18)
11. Incidence of graft loss for technical reasons, e.g. renal artery or vein thrombosis
12. One year patient survival
13. Length of hospital stay

Overall study start date
06/04/2011

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. Patients who receive a kidney transplant from a controlled or uncontrolled cardiac-death deceased donor
2. Recipient over the age of 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Sequential trial design - maximum of 270 recipients

Key exclusion criteria
1. Lack of informed consent
2. Positive crossmatch
3. Previous recipient of non-kidney solid-organ transplant

Date of first enrolment
06/04/2011

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Research And Development Department
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Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
NHS Blood and Transplant (UK) (ref: UKT07/2)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		23/11/2018	23/11/2018	No	No